Eastside Cardiology Associates

Cardiovascular Diseases

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September 14, 2007

State of Washington Department of Health
and Health Management Associates

Dear State of Washington Department of Health and Health Management Associates:

I hold five major areas of concern in reviewing Health Management Associates study for the Department of Health on offsite coronary intervention. I will list the five areas and then expound on each:

1. Corrections and clarification of information presented.
2. Respect for the scope of work guidelines requested.
3. Complete scope of work.
4. Remove opinions not backed by evidence.
5. Re-submit a corrected document to the Department of Health from which the department will draft the straw-man rules.

Correction and clarification of information.

Under section three introduction page three, change the following statement: "The current rate of immediate CABG post PCI is now less than 1%" to "The current rate of immediate CABG post PCI is now 3 per 1,000"

Under introduction page 4, change the statement: "Invasive procedure that is resource intensive" to "Invasive procedure that can be resource intensive in hospitals that do not currently have cardiac catheterization laboratories."

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On page 4, correct the line "reluctance of expert panels, professional societies, and governmental regulatory agencies to fully endorse and permit the provision of elective PCI in hospitals without on site cardiac surgery" to "reluctance of expert panels, professional societies to fully endorse and permit the provision of elective PCI in hospitals without on sight cardiac surgery." The reason for this correction is there are governmental regulatory agencies in many states that have endorsed and permitted elective PCI in hospitals without on-sight cardiac surgery.

Section 9. Correction the entire paragraph and subsequent references that the University of Washington School of Medicine is the only cardiovascular disease, cardiology and interventional cardiology fellowship program in the Washington, Alaska, Montana, Idaho, and Oregon regions of the Northwestern United States.

Respect the Scope of Work.

The State of Washington specifically contracted with Health Management Associates to conduct and evidence based review that supports standards for the performance of adult elective percutaneous coronary intervention in Washington Hospitals that do not provide on sight cardiac surgery. The scope of work did not include reviews or opinions offered on whether or not coronary interventions should be allowed. These sections should be categorically removed from the document before resubmission to the State Department of Health.

Complete the Scope of Work.

In completing the evidenced based review requested by the Department of Health, there are some important omissions and incomplete analysis that Health Management Associates failed to address. The first and foremost is their analysis of volume evidence. The analysis provided by health management associates was incomplete and their methodology for arriving at their recommended number of three to four hundred was not revealed. I am currently conducting an independent review of World and US literature on this topic and will continue to work with Dr. Gallant and others to provide these results to the Washington State Department of Health.

Another area that Health Management Associates did not address is the regulations required by other states that currently permit off site coronary intervention. Appendix A is a review of those state regulations that may be of great value to the State of Washington Department of Health.

In Health Management Associates' discussion of unmet need, they identified patients and groups of patients that may have unmet services. However, the largest group of patients was not addressed in this study and that is the group of patients that present at nonsurgical hospitals with intermediate coronary syndrome. At the public hearing on September 12, I presented one of the worst examples of the results of the prohibitions placed by the current Washington State law and why it needs to be changed. This was the story of a 46-year-old man who presented to Evergreen Hospital with an intermediate coronary syndrome. He was unstable, but not having an acute myocardial infarction. Therefore, his vessel could not be opened at Evergreen that would have taken on the average 10 additional minutes to the catheterization study. Instead, the patient had to be transferred to a nearby surgical hospital. Unfortunately, because he was on blood thinners, in the process of transport, he developed a large bleeding reaction at the site where his catheterization was performed in his right leg. He had lost about two units of blood into his leg and needed blood transfusions and we had to stop the blood thinners because we could not control the bleeding. Shortly thereafter, the patient suffered a complete myocardial infarction with ST elevation. The two labs at the destination hospital were both tied up in intensive

procedures, and were not estimated to be free for approximately two hours. I therefore made the decision to move the patient to cardiac surgery for emergency bypass as I felt this could be done more quickly than transferring him to a third hospital downtown for a coronary intervention. Unfortunately before he could arrive at bypass, he had cardiac arrest and died. I was the bearer of the news of his death to his wife and his three young daughters, but the story did not end there. The ripple effects of his death were quite profound. This event occurred approximately a decade ago, and I saw his daughter, who is approximately 20 for chest pain not long ago. I did not recognize her but she reminded me of the events that had occurred. When I asked how she, her sisters, and her mother were doing, she explained to me that after their father's death, they lost their home and they moved back with family to Tennessee. Her mother became an alcoholic, her one sister committed suicide at the age of 16. She herself moved back to Washington and has lost complete contact with her remaining sister. Although this is the most extreme example of what may happen, the fact that it did happen and was preventable is tragic.

What we do know is that at Evergreen Hospital, we transfer about 100 patients who come in for emergency situations and are unstable. They are not having myocardial infarctions and, according to state law, PCI cannot be done at Evergreen. Approximately 5% or 1 out of 20 patients suffers adverse outcomes because of the current restrictions. These include complications such as groin bleeds in transport, myocardial infarction while waiting at another hospital before getting to another catheterization lab, increased radiation exposures because of having to repeat a second procedure, increased contrast dose resulting in renal more insufficiency, increased cost due to expensive transport, an additional hospital day (putting a strain on the medical economic system), increased stress to family members (who are often elderly) and the list goes on.

In the newly proposed legislation it is estimated that 3 out of 1,000 patients who have coronary intervention will require emergency transport and will need emergency bypass. This compares to our current system where 50 out of 1,000 patients currently who are experiencing adverse consequences, sometimes life-threatening. There is no perfect solution, but it is far better to deal with 3 out of 1,000 patients in an offsite hospital who may need emergency surgery versus 50 out of 1,000 patients who are currently having major problems. This will improve the care for the patients in all the communities who currently are living under these adverse restrictions.

I request that Health Management Associates include a paragraph describing how intermediate coronary syndrome comprises a group of patients who currently have unmet access for coronary intervention.

Under section 8, page 15, Health Management Associates discusses the conditions that create high patient risk and high lesion risk. However, the issue here is not whether patients are at risk or not at risk, but whether there are specific factors that raise their risk for acute closure, necessitating emergency transport from a nonsurgical hospital to a surgical hospital, or conditions where a small delay in transport could result in a significant adverse outcome. The conditions they list on page 15 that are not relevant to the discussion include "renal failure, recent CVA, coagulation disorders, and other serious complicated or uncontrolled medical conditions". Although these do raise patient risk over the course of their treatment, it does not raise procedural risk for emergency bypass. However, the other conditions they listed do raise risk for emergency transportation or where small delays may result in a significant adverse outcome.

Vessel morphology that increases risk to the patient's long term restenosis rate has nothing to do with procedural complications necessitating emergency bypass and include: "diffuse disease greater than 2 cm in length, tortuosity of proximal segments, more than moderate calcification of the stenosis in a proximal segment, and what they called other features that were judged to impede stent implantation". However, the remaining lesion risks are correct.

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Section 9, page 18. The cost and financial sustainability and feasibility is such an inadequate evaluation of this issue, that it should be completely removed from this document unless Health Management Associates are willing to complete a reasonable analysis of the issue.

Health Management Associates has suggested that as many as 40% of Washington's existing programs could fall below volume standard should new programs open. They have also suggested that the University of Washington currently is barely meeting interventional training criteria. We would ask that Health Management Associates provide the data behind these statements so they can be objectively reviewed. How were the calculations done that would effect 40% of programs and what are these calculations? What are the volumes of the University of Washington and what are the requirements? What has the University of Washington done to partner with other hospitals in the community to provide training for their fellows? All of these issues need to be addressed to complete the scope of work requested by the State of Washington Department of Health.

Remove opinions not backed by evidence.

Health Management Associates has suggested on page 21, section 7 that hospitals must have two fully equipped catheterization laboratories. There is no evidence to support this contention improves quality, and it certainly would dramatically raise cost for some institutions. Unless evidence is presented, this should be removed.

On page 21, section 8 it is suggested that all interventionalists be board certified in interventional cardiologist. The majority of interventionalists can no longer obtain interventional board so they have been closed by the American Board. We discussed this at the public meeting on September 12, and we believe Health Management Associates had intended to require either interventional boards or lifetime experience of greater than 500. We would like the document to reflect the correction.

On page 24, section 16 it has been suggested that OR backup be attainable in less than 90 and ideally less than 60 minutes. We would like to see the data that has led to that recommendation or have this section removed.

Resubmission of a corrected document.

Since the Department of Health is going to use the Health Management Associate study on which to draft straw-man rules, it is imperative that the state of Washington has an accurate and complete document in order to draft the rules with the greatest validity as a starting point for discussion. We therefore respectively request that Health Management Associates submit a document that addresses the above concerns before straw man rules are adopted.

Finally, there are several issues that have not yet been addressed. First of all, cardiac electrophysiology is a cardiac interventional procedure that has currently been linked in Washington with requirement to be done in hospitals with open-heart surgery. Discussions on whether electrophysiology will follow the new rules, or remain under an old rule will need to be decided.

Secondly, this document does not address the concern that all interventional cardiologists performing offsite intervention need to be privileged in performance of intraaortic balloon pumping, pericardial centesis, and most importantly, have either experience or have attended courses on the placement of covered stents, which his a method used to seal perforations. The C-port Study requires all institutions

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participating in the study and all cardiologists participating to have competency in these areas, and these need to be added as requirements in offsite and hospitals.

Thirdly, we need to discuss the time to reach target volumes. The push to reach target volumes too soon may create a pressure for institutions to do higher risk patients or lesions than they might otherwise have attempted. This could lead to adverse patient outcomes. We will need to find a balance between time to achieve volumes and autonomy.

Fourth, this document recommends that all hospitals be enrolled in a randomized trial, and yet, randomized trials may not exist at the time that the hospital is enrolled and needs to be addressed. Where is the data showing this improves quality?

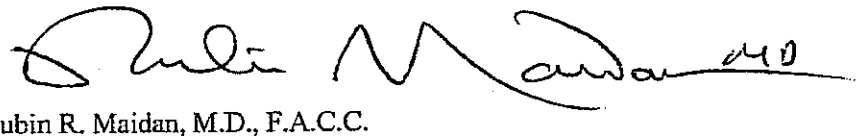
Another issue is quality assurance benchmarks; what type of data entry monitoring will be necessary, whether to use COAP or national registries, whether to use local, state, or national benchmarks for complication rates.

How can we assist the University Hospital in its training programs? What role can the community cardiologists and community hospitals play in training?

What role can the community of cardiologists assist Swedish Hospital and the University Hospital in research protocols and other ways to support important institutions in our region.

How do we address the large discrepancy of standards that we are creating between hospitals and cardiologists with open heart vs. those without (in terms of PCI volumes)? The difference is that non open-heart programs can be shut down if benchmarks are not met, but open heart hospital programs are immune to these pressures.

Sincerely,



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RRM/mw

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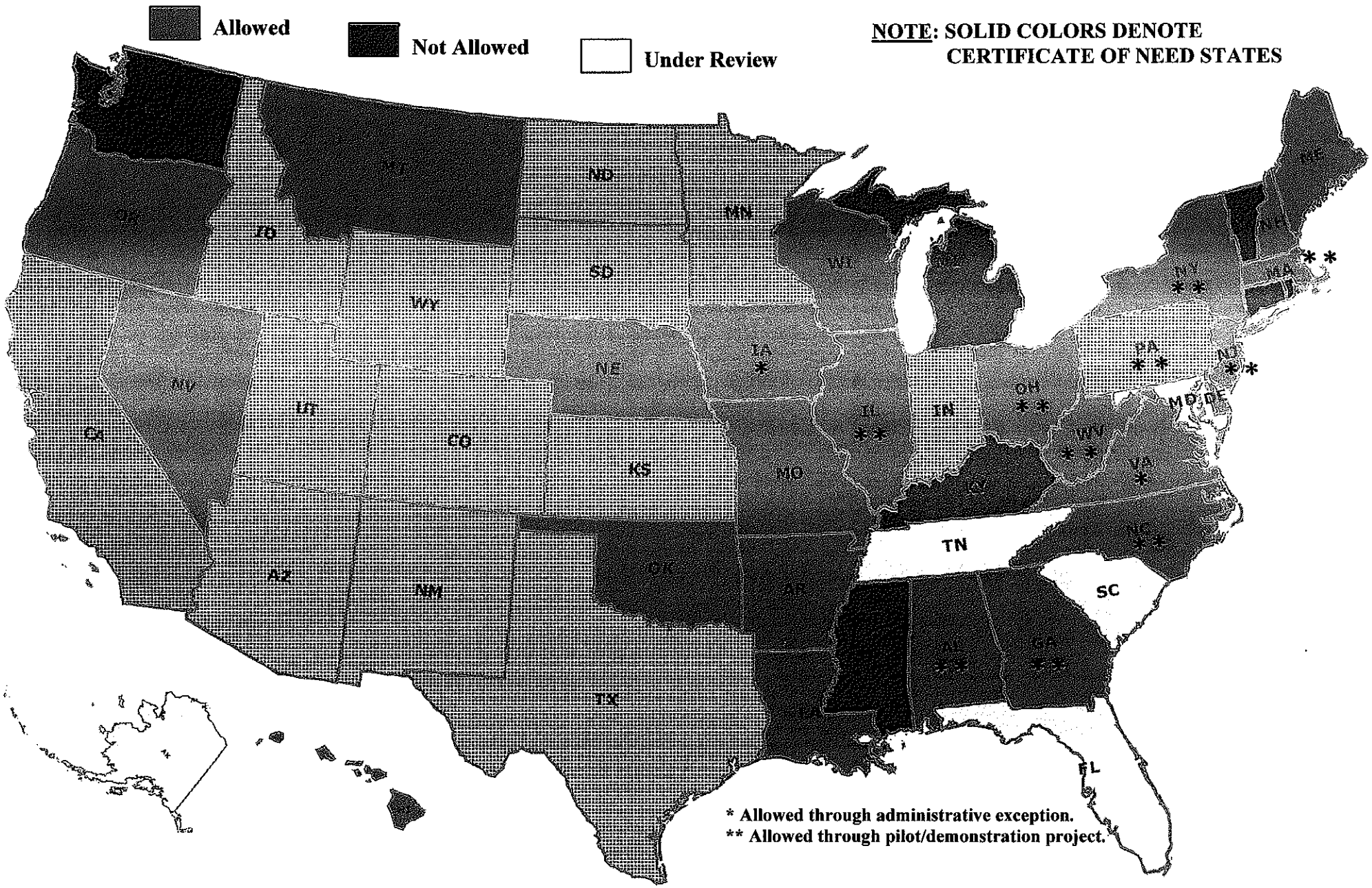
Appendix A
Non-Emergency Angioplasty in Hospitals Without On-Site Heart Surgery
Regulation by State as of January, 2007

Non-Emergency Angioplasty in Hospitals Without On-Site Heart Surgery
Regulation by State as of January, 2007



The above information was collected through direct contact with state officials in each state. Contact information is available for each state should questions arise.

Non-Emergent Angioplasty in Hospitals Without On-Site Heart Surgery
Regulation by State as of January, 2007

State	CN State Y/N	As Listed on Map	Details
Alabama	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study. Also allow through administrative exception. This procedure not subject to CN review for rural hospitals.
Alaska	Y	Under Review.	Under Review. State is contemplating allowing under specific circumstances via administrative exception.
Arizona	N	Allowed.	Allowed. Do not regulate these procedures.
Arkansas	Y	Allowed.	Allowed. Do not regulate these procedures.
California	N	Not Allowed.	Not Allowed. Only emergency procedures allowed in hospitals without on-site heart surgery.
Colorado	N	Allowed.	Allowed. Do not regulate these procedures.
Connecticut	Y	Not Allowed.	Not Allowed. Only emergency procedures allowed in hospitals without on-site heart surgery.
Delaware	Y	Allowed.	Allowed. Subject to Certificate of Need review and approval.
Florida	Y	Under Review	Under Review. Rule change pending.
Georgia	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
Hawaii	Y	Allowed.	Allowed. Not subject to CN.
Idaho	N	Allowed.	Allowed. Do not regulate these procedures.
Illinois	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
Indiana	N	Allowed.	Allowed. Do not regulate these procedures.
Iowa	Y	Allowed through administrative exception.	Allowed through administrative exception. While not permitted by rule, CN board approves hospitals without on-site heart surgery to perform non-emergent angioplasty on a case by case basis.
Kansas	N	Allowed.	Allowed. Do not regulate these procedures.
Kentucky	Y	Not Allowed.	Not allowed. Only emergency procedures allowed in hospitals without on-site heart surgery.
Louisiana	Y	Allowed.	Allowed. Not subject to CN.
Maine	Y	Allowed.	Allowed. Not subject to CN.
Maryland	Y	Under Review	Decision on participating in Johns Hopkins C-Port Study expected 2/2007.
Massachusetts	Y	Allowed through pilot/demonstration project.	Allowed through state-specific pilot/demonstration project. .
Michigan	Y	Not Allowed.	Not Allowed. Only emergency procedures allowed in hospitals without on-site heat surgery.
Minnesota	N	Allowed.	Allowed. Do not regulate these procedures.
Mississippi	Y	Not Allowed	Not allowed. Only allowed through grandfathering.
Missouri	Y	Allowed.	Allowed. Not subject to CN.
Montana	Y	Allowed.	Allowed. Not subject to CN.
Nebraska	Y	Allowed.	Allowed. Not subject to CN.
Nevada	Y	Allowed.	Allowed. Not subject to CN.
New Hampshire	Y	Allowed.	Allowed. Not subject to CN.

State	CN State Y/N	As Listed on Map	Details
New Jersey	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
New Mexico	N	Allowed	Allowed. Do not regulate these procedures.
New York	Y	Allowed through pilot/demonstration project.	Allowed through state-specific pilot/demonstration project.
North Carolina	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
North Dakota	N	Allowed.	Allowed. Do not regulate these procedures.
Ohio	Y	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
Oklahoma	Y	Allowed.	Allowed. Not subject to CN.
Oregon	Y	Allowed.	Allowed. Not subject to CN.
Pennsylvania	N	Allowed through pilot/demonstration project.	Allowed through pilot/demonstration project. Participating in Johns Hopkins C-Port Study.
Rhode Island	Y	Not Allowed.	Not Allowed.
South Carolina	Y	Under Review.	Decision on participating in Johns Hopkins C-Port Study expected 2/2007.
South Dakota	N	Allowed.	Allowed. Do not regulate these procedures.
Tennessee	Y	Under Review.	Under Review. New guidelines pending.
Texas	N	Allowed.	Allowed. Do not regulate these procedures.
Utah	N	Allowed.	Allowed. Do not regulate these procedures.
Vermont	Y	Not Allowed.	Not Allowed.
Virginia	Y	Allowed through administrative exception.	Allowed through administrative exception. While State Health Plan prohibits performance of elective interventions in hospitals without on-site heart surgery, the Commissioner of Health has allowed on a case by case basis.
Washington	Y	Not Allowed.	Not allowed. Only emergency procedures allowed in hospitals without on-site heart surgery.
West Virginia	Y	Allowed through pilot/demonstration project.	Allowed through state-specific pilot/demonstration project.
Wisconsin	Y	Allowed.	Allowed. Not subject to CN.
Wyoming	N	Allowed.	Allowed. Do not regulate these procedures.

The above information was collected through direct contact with state officials in each state. Contact information is available for each state should questions arise.